UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,587	07/10/2002	Leszek Wojnowski	VOS-30	7615

1473 7590 09/29/2006

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
1251 AVENUE OF THE AMERICAS FL C3
NEW YORK, NY 10020-1105

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,587	WOJNOWSKI ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,12,13,37,39 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-8, 12, 13, 37, 39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to the Amendment

The Amendment filed on 07/06/2006 in response to the previous Non-Final Office Action (04/06/2006) is acknowledged and has been entered.

Claims 1, 3-8, 12-13, 37 and 39-40 are currently pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8, 12-13, 37 and 39-40 remain rejected as vague and indefinite for reciting the term CYP3A4 as the sole means of identifying the claimed molecule. The use of laboratory designations only to identify a particular molecule renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct molecules. The rejection can be obviated by amending the claims to specifically and uniquely identify CYP3A4, for example, by SEQ ID NO: and function of CYP3A4.

In response to this argument, Applicants contend that by providing the complete name of the variant cytochrome P450 3A4 (CYP3A4) monooxygenase gene, along with its GenBank accession number, it would be clear to one of skill in the art-on this basis lone-what gene is being referred to. These arguments have been carefully considered, but are not found persuasive.

In response to Applicants assertion that the specification refers to the sequence of CYP3A4 by GenBank accession number CYP3A4 which provides public access to the gene sequence, the Examiner acknowledges that the specification refers to the sequence of CYP3A4 by GenBank accession number CYP3A4. Yet, the Examiner recognizes that different laboratories may use the same laboratory designations to define completely distinct molecules. As such, the use of the laboratory designation, CYP3A4, only to identify a particular molecule renders the claim indefinite.

Moreover, it is well known in the art that accession numbers can be altered, deleted, amended, or revised over time by various inventors. Hence, one of ordinary skill in the art and/or competitors would be unable to discern the meets and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-7, 12-13, 37, and 39-40 remain rejected under 35 U.S.C. 102(e) as being anticipated by Larossa et al. (U.S. 6,025,131, 1996).

Larossa et al. teach a polynucleotide having, from nucleotides 134 to 144, the presently claimed polynucleotide of SEQ ID NO: 90 (Columns 33 and 34, see attached sequence comparison for sequence identifier 12). The Patent further teaches (column 4, lines 53-55, column 11, lines 2-14, and Figure 1) a vector comprising the polynucleotide further operatively linked to an expression control sequence which allows for the expression in prokaryotic or eukaryotic cells. Moreover, Larossa et al. teach (page 4, lines 56-58) host cells with are genetically engineered with a vector comprising a polynucleotide operatively linked to an expression control sequence. Furthermore, the patent teaches (column 8, lines 60-67) a nucleic acid molecule which is complementary to the polynucleotide as the result of expression of the gene product, wherein the gene product is a protein. In addition, Larossa et al. (column 4, line 59 to column 5, line 2) provide a diagnostic composition comprising a probe useful for detecting chemical compounds, wherein said probe comprises a the polynucleotide operatively linked to a luminescent reporter gene complex. Lastly, the patent teaches a method for producing cells comprising genetically engineering cells with the polynucleotide (column 13, line 50 to column 14, line 34).

Query Match 100.0%; Score 11; DB 3; Length 205;
Best Local Similarity 100.0%; Pred. No. 1.1e+03;

```
Qy          1 TGAAATGCTCA 11   (SEQ ID NO: 90)
              ||||||||||||
Db        134 TGAAATGCTCA 144   (Larossa's SEQ ID NO: 12)
```

Claim 37 is rejected under 35 U.S.C. 102(e) as being anticipated by Mittman et al. (US 6,821,724, 1999).

Mittman et al. teach a nucleic acid probe consisting of 25 nucleotides in length and comprising the patentably claimed nucleotide sequence of SEQ ID NO: 90 or a complementary sequence as shown below.

US-6,821,724 (SEQ ID NO:71432)

Query Match 100.0%; Score 11; DB 4; Length 25;
Best Local Similarity 100.0%; Pred. No. 8.1e+02;
Matches 11;

```
Qy          1 TGAAATGCTCA 11 (SEQ ID NO: 90)
              ||||||||||||
Db         12 TGAAATGCTCA 2 (SEQ ID NO: 71432)
```

In response to the rejection of claims 1, 4-7, 12-13, 37, and 39-40 under USC 102 (e), Applicants contend that applicants have discovered a phenotypic change associated with an amino acid substitution resulting from a nucleotide change in a variant of the CYP3A4 gene, wherein a portion of the CYP3A4 nucleotide sequence containing the polymorphism that produces the variant polypeptide with an impaired expression and enzymatic activity is provided in SEQ ID NO: Applicants further assert that neither Larossa nor Mittman describe or refer to a CYP3A4 polypeptide and further, neither of the sequences referred to in Larossa and Mittman is within a CYP3A4-encoding sequence. Therefore, Applicants assert that these documents cannot anticipate the subject matter of the claim directed to an isolated polynucleotide that comprises the nucleotide sequence of SEQ IDNO: 90 and encodes a variant CYP3A4 polypeptide or fragment.

These arguments have been carefully considered, but are not found persuasive.

Regarding Applicants assertion that the sequences disclosed by Larossa and Mittman cannot anticipate the subject matter of the amended claims because the polynucleotides are not a polynucleotide encoding a variant of a CYP3A4 polypeptide or fragment thereof, the Examiner acknowledges and agrees with Applicants arguments that the references do not explicitly recite a polynucleotide which encodes a variant of a CYP3A4 polypeptide or fragment thereof. However,

the Examiner recognizes that both of the sequences disclosed by the two references comprise the nucleotide sequence of SEQ ID NO: 90 and therefore, anticipate part (a) of the claim 1 which recites a polynucleotide comprising the nucleotide sequence of SEQ ID NO: 90. Thus, although Larossa does not specifically teach that the polynucleotide encodes a variant of a CYP3A4 polypeptide or fragment thereof, the claims are drawn to the product *per se* and inherently, such a polynucleotide comprising SEQ ID NO: 90 would encode a CYP3A4 polypeptide. As such, the claimed polynucleotide appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Therefore, No claim is allowed.

All other rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon J Fetterolf, PhD
Patent Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER